

REMARKS/ARGUMENTS

The Office Action mailed April 30, 2004 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. Claims 10-35 were subject to a restriction requirement in the Office Action mailed 05/15/2002 as being directed to a non-elected invention(s). Claims 10-35 stand withdrawn from consideration in this application. The claims presented for examination in this application are: claims 1-9 and 36-43.

35 U.S.C. 102 Rejection in Paragraph 8 of Office Action

In numbered paragraph 8 of the Office Action mailed April 30, 2004, claims 1-3, 5-6, 36, and 40 were rejected under 35 U.S.C. 102 as allegedly being anticipated by the Pyle et al reference (United States Patent No. 5,821,066).

A number of the steps of Applicants' amended claims 1-3, 5-6, 36, and 40 are not shown by the Pyle et al reference. For example, the following steps of Applicants' single independent claim in this group of rejected claims, amended claim 1, are not shown by the Pyle et al reference:

**"providing a multiplicity of optically encoded microbeads"** - - Note that the Pyle et al reference uses "immunomagnetic beads" and that "immunomagnetic beads" are not "optically encoded microbeads."

**"providing said microbeads with a capture ligand,"**

**"attaching at least some of said optically encoded microbeads to a disposable capture substrate containing an array of individual attachment sites for attaching said optically encoded microbeads thereto wherein each individual attachment site captures a single optically encoded micro bead with capture ligand, bioagent-specific antibody, fluorescent labeled antibody, and any targeted biological sample"**

**"inserting said substrate into an optical detection system," or**

**"optically decoding said microbeads for detection and measurement of the targeted biological sample."**

The method of the Pyle et al reference that utilize some form of bead is set out below. Note that Applicants' steps in amended independent claim 1 that are set out above do not appear in the Pyle et al reference method described below.

- a) mixing immunomagnetic beads comprising an antibody which specifically binds to a target bacteria with a liquid sample comprising said target bacteria;
- b) allowing said liquid sample to interact with the beads for up to an hour;
- c) placing the sample in a magnetic separator which causes the magnetic beads to which target bacteria have attached to separate from the liquid sample;
- d) aspirating the liquid from the liquid sample, leaving the beads with bacteria attached;
- e) washing the beads with a solution which removes loosely bound bacteria and other particles from the liquid sample;
- f) mixing beads with bacteria attached with a fluorochrome dye specific for the detection of respiring bacteria;
- g) treating bacteria on the beads with a fluorescent stain or a specific fluorescent conjugated antibody;
- h) mounting said sample for examination by epifluorescent microscopy, in which a suitable light filter system is used to excite the fluorochrome dye and fluorochrome labeled antibody to fluoresce; and
- i) quantifying said respiring target bacteria. (Col. 12, lines 45-67 and Col. 13, lines 1)

As stated in Verdegaal Bros. v. Union Oil Co of California, 814 F.2<sup>nd</sup> 628, 631 USPQ 1051, 1053 (Fed. Cir. 1987), "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." Since the steps described above are not

shown by the Pyle et al reference, the Pyle et al reference does not support a 35 USC §102(b) rejection.

35 U.S.C. 103 Rejection in Paragraph 11 of Office Action

In numbered paragraph 11 of the Office Action mailed April 30, 2004, claims 41-43 were rejected under 35 U.S.C. 103 as allegedly being unpatentable over the primary reference, Pyle et al (United States Patent No. 5,821,066), and the secondary reference, Nazareth et al (United States Patent No. 6,319,676).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Pyle et al reference and Applicants' invention defined by claims 41-43 are that the primary Pyle et al reference does not show the following steps of Applicants' independent claim 41:

**"providing a quantity of optically encoded microbeads,  
adding a capture ligand to said microbeads,"**

**"providing a disposable capture substrate containing an array  
of attachment sites for attaching said microbeads thereto,"**

**"inserting said disposable capture substrate containing an  
array of attachment sites into said contained microbeads for  
capturing said microbeads,"**

**"inserting said disposable capture substrate into a detection  
system," or**

**"optically decoding said microbeads for identification and  
measurement of the biological molecules attached to said  
microbeads."**

The primary Pyle et al reference does not have steps of the invention set out above. The Pyle et al reference uses "immunomagnetic beads" and "immunomagnetic beads" are not **"optically encoded microbeads."** The Pyle et al reference does not use Applicants' claimed **"disposable capture substrate containing an array of attachment sites for attaching said microbeads thereto."** The Pyle et al reference simply states, "mounting said sample for examination by epifluorescent microscopy" and "mounting" is not Applicants' claimed **"disposable capture substrate"** nor does it have Applicants' claimed **"an array of attachment sites for attaching said microbeads thereto."** Consequently, the Pyle et al reference does not have Applicants' steps of **"inserting said disposable capture substrate into a detection system,"** or **"optically decoding said microbeads for identification and measurement of the biological molecules attached to said microbeads."**

The Nazareth et al reference does supply the missing steps. There is no teaching to combine the primary Pyle et al reference and the secondary Naareth et al reference.

Applicants believe they have provided a full and complete response to the rejection of claims 41-43 under 35 USC 103 stated in numbered paragraph 11 of the Office Action mailed April 30, 2004.

#### 35 U.S.C. 112 Rejection

In numbered paragraph 14 of the Office Action mailed April 30, 2004, claims 1-8 and 41-43 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants have amended the claims to address the issues raised by the Examiner in subparagraphs 14. a-d. An antecedent basis for the term "contained microbeads" has been provided. The step of "placing said optically encoded microbeads in a disposable bead pack" is now a separate step.

The "assay" portion of claim 8 has been deleted.

Applicants believe they have provided a full and complete response to the rejection of claims 1-8 and 41-43 under 35 USC 103 stated in numbered paragraph 14 of the Office Action mailed April 30, 2004.

35 U.S.C. 102 Rejection in Paragraph 16 of Office Action

In numbered paragraph 16 of the Office Action mailed April 30, 2004, claims 1 and 8 were rejected under 35 U.S.C. 102 as allegedly being anticipated by the Seul et al reference (United States Patent No. 6,387,707).

A number of the steps of Applicants' amended claims 1 and 8 are not shown by the Seul et al reference. The method of the Seul et al reference does not utilize "optically encoded microbeads with a capture ligand," or "a disposable capture substrate containing an array of individual attachment sites for attaching said optically encoded microbeads thereto," or "each individual attachment site captures a single optically encoded micro bead with capture ligand, bioagent-specific antibody, fluorescent labeled antibody, and any targeted biological sample."

As stated in Verdegaal Bros. v. Union Oil Co of California, 814 F.2<sup>nd</sup> 628, 631 USPQ 1051, 1053 (Fed. Cir. 1987), "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." Since the steps described above are not shown by the Seul et al reference, the Seul et al reference does not support a 35 USC §102(b) rejection.

35 U.S.C. 103 Rejection in Paragraph 19 of Office Action

In numbered paragraph 19 of the Office Action mailed April 30, 2004, claims 1 and 4 were rejected under 35 U.S.C. 103 as allegedly being unpatentable over the primary reference, Marshall (United States Patent No. 5,236,826), and the secondary reference, Okusa et al (United States Patent No. 4,952,520).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Marshall reference and Applicants' invention defined by claims 1-4 are that the primary Marshall reference does not show the following steps of Applicants' independent claim 1:

"providing a multiplicity of optically encoded microbeads," or  
"providing said optically encoded microbeads with a capture ligand," or  
"attaching at least some of said optically encoded microbeads to a disposable capture substrate containing an array of individual attachment sites for attaching said optically encoded microbeads thereto wherein each individual attachment site captures a single optically encoded micro bead with capture ligand, bioagent-specific antibody, fluorescent labeled antibody, and any targeted biological sample."

The Marshall reference uses "particles" and does not show Applicants step that utilizes "optically encoded microbeads." The Marshall reference uses a "filter" and "some of the particles will remain blocked on its surface, whether because of clumping, aggregation or random nonuniformly sized particles." (Col 5, lines 19-21 of the Marshall Reference) The filter pores of the Marshall reference capture multiple particles, not a single particle.

The Okusa et al reference does supply the missing steps. There is no teaching to combine the primary Marshall reference and the secondary Okusa et al reference.

Applicants believe they have provided a full and complete response to the rejection of claims 41-43 under 35 USC 103 stated in numbered paragraph 11 of the Office Action mailed April 30, 2004.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated April 30, 2004 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Eddie E. Scott", is written over a horizontal line.

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